K103464

510(k) Summary

DEC 2 2 2010

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR Part 807, Section 807.92(c).

Applicant:

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Alternate Contact: Fred Boucher, Director, RA
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Date Prepared: November 22, 2010

Device Information:

Trade Name:	Medtronic Invatec PACIFIC XTREME™ PTA Balloon
Common Name:	Percutaneous Transluminal Angioplasty Catheter
Regulation Name:	Percutaneous Catheter
Classification:	II
Classification Panel:	Peripheral
Regulation Number:	21 CFR 870.1250
Product Code:	LIT, DQY

Predicate Devices:

Invatec SUBMARINE PLUS PTA Balloon catheter (K042537)
Invatec AMPHIRION DEEP OTW PTA Balloon Dilatation Catheter (K083919)
Invatec ADMIRAL XTREME PTA Balloon Catheter (K100921)

Device Description:

The PACIFIC XTREME™ PTA Balloon Dilatation Catheter is an over-the-wire Percutaneous Transluminal Angioplasty (PTA) catheter consisting of a proximal hub, dual lumen coaxial shaft, and a distal dilatation balloon. The PACIFIC XTREME™ PTA Balloon Dilatation Catheter is compatible with guidewires with a maximum diameter of 0.018" and with 4F and 5F introducer sheaths, depending on the diameter and balloon length of the dilatation balloon. The catheter is provided with a hydrophilic coating and is available in useable catheter lengths of 90 and 130cm.

Indication for Use:

The PACIFIC XTREME PTA Balloon Dilatation Catheter in 150mm, 200mm, 250mm and 300mm balloon length is intended to dilate stenoses in the femoral, popliteal, and infrapopliteal arteries.

Technological Characteristics:

The PACIFIC XTREME™ PTA Balloon Dilatation Catheter is an over-the-wire percutaneous transluminal angioplasty (PTA) catheter. The catheter is compatible with .018" guidewire. The technological characteristics of the PACIFIC XTREME™ PTA Balloon Dilatation Catheter are substantially equivalent to those of the Submarine Plus PTA Balloon catheter (K042537), Amphirion Deep PTA Balloon Catheter (K083919), and the Admiral Xtreme PTA Balloon Catheter (K100921).

Summary of Bench Testing:

In vitro bench testing of the PACIFIC XTREME™ PTA Balloon Dilatation Catheter was conducted in accordance with Medtronic Invatec Risk Analysis and all applicable FDA guidance documents and ISO standards, testing included:

- Minimum Balloon Burst Strength (RBP)
- Balloon Compliance (diameter vs pressure)
- Balloon Inflation and Deflation time

- Balloon Fatigue (repeat balloon inflations)
- Flexibility and Kink Test
- Torque Strength
- Balloon Preparation
- Guidewire Compatibility
- Coating Durability
- Coating Lubricity
- Catheter Diameter-balloon profile usable length
- Tensile Strength
- Catheter Body Burst Pressure
- Introducer Sheath Compatibility

Summary of Biocompatibility Testing:

The PACIFIC XTREME™ PTA Balloon Dilatation Catheter is an externally communicating device, which contacts circulating blood for the limited contact duration (<24hours).

Biocompatibility testing was conducted on finished PACIFIC XTREME™ PTA Balloon Catheters in accordance with ISO 10993-1 , "Biological Evaluation of Medical Devices part 1:Evaluation and testing," as specified in the FDA Blue Book Memorandum #G95-1 and FDA guidance: Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters (May 30 2008) All testing documented below was conducted in accordance with the provisions of the FDA GLP regulations 21 CFR 58.

The following Biocompatibility tests were completed and passed:

- Cytotoxicity Study
- Maximisation Sensitization Study
- Intracutaneous Study
- Systemic Toxicity Study
- Material Mediated Pyrogen Study
- Hemolysis Study
- In Vivo Thromboresistance Study
- Lee White Coagulation Test
- Complement Activation

Assessment of non-clinical performance data for equivalence:

Bench and biocompatibility testing were conducted according to the recommendations from relevant FDA guidance to demonstrate that the PACIFIC XTREME™ PTA Balloon Dilatation Catheter acceptance criteria and performed equally to the predicate devices. No new safety or effectiveness issues were raised during the testing.

Summary of Clinical Data:
No clinical investigation has been performed for this device.

Conclusion from Data:
Medtronic Invatec has demonstrated that the PACIFIC XTREME™ PTA Balloon Dilatation Catheter is substantially equivalent to the predicate devices based on its indications for use and fundamental scientific technology. Testing demonstrates that the PACIFIC XTREME™ PTA Balloon Dilatation Catheter device is safe, effective and performs as well as the predicate devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Medtronic, Inc.
C/O Heather Morose
Associate Regulatory Specialist
37A Cherry Hill Drive
Danvers, MA 01923

DEC 2 2 2010

Re: K103464
Trade/Device Name: PACIFIC XTREME™ PTA Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: LIT, DQY
Dated: November 22, 2010
Received: November 24, 2010

Dear Ms. Morose:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

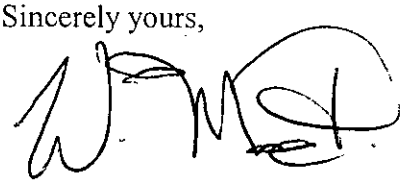
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Medtronic

Indications for Use

DEC 2 2 2010

510(k) Number (if known): K103464
Device Name: PACIFIC XTREME™ PTA Balloon Dilatation Catheter
Indications for Use:
The PACIFIC XTREME PTA Balloon Dilatation Catheter in 150mm, 200mm, 250mm and 300mm balloon length is intended to dilate stenoses in the femoral, popliteal, and infrapopliteal arteries.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K103464